Section 2. PREDICT Policies and Plans

Confirmation of Knowledge

When you are familiar with the information in this guide, take the PREDICT quiz in ***Section 8.4.1. PREDICT Policies and Plans***.

Table of Contents

Section 2.1. PREDICT Biological Sample and Diagnostic Data Sharing Policy

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This document was made possible by the generous support of the American people through the United States Agency for International Development (USAID) Emerging Pandemic Threats PREDICT. The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

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Suggested Citation Form: PREDICT One Health Consortium 2016. PREDICT Operating Procedures: Biological Sample Sharing and Submission and Diagnostic Data Sharing.

February 4, 2015

Section 2.1.1 PREDICT Collaboration

PREDICT is a cooperative agreement between the US Agency for International Development (Emerging Pandemic Threats Program; USAID EPT) and a consortium comprised of the University of California, Davis, Wildlife Conservation Society, EcoHealth Alliance, Metabiota, Inc. and the Smithsonian Institution, as well as collaborating and subawardee institutions and organizations. The PREDICT consortium and their partners bring particular areas of subject and geographic expertise to the PREDICT endeavor, and all have committed to engaging in transparent communications and activities for the duration of the project.

Section 2.1.2. Purpose of this Policy

Acquiring and analyzing biological samples from humans, livestock and wildlife (hereafter referred to as "samples") is a primary PREDICT activity, and data obtained through laboratory analyses of these samples for known or emerging zoonotic pathogens is integral to the success of the project.

PREDICT personnel proactively collect samples at targeted high-risk human/animals (wildlife and livestock) interfaces, and gain access to samples from humans, livestock and wildlife through existing and new partnerships with outside (non-PREDICT) researchers (individuals, institutions, agencies, and organizations) working on species or in an areas of particular relevance to PREDICT project goals.

In the interest of achieving PREDICT objectives without causing professional misunderstandings that could undermine relationships and jeopardize PREDICT and the USAID EPT, and recognizing that PREDICT depends upon access to samples from, and data generated by, partnerships, it is imperative to clarify and agree on sample, data and sequence sharing guidelines, as well as terms for publishing jointly- generated data. Furthermore, it is possible that the results of this work may be commercially exploited. **It is an explicit goal of this document to define who owns Intellectual Property Rights (IP) to the samples, sequences, isolates, and techniques discovered or developed during this study.**

Section 2.1.3. Guiding Principles

Sharing information among PREDICT partners, and with the USAID EPT, in as timely a manner as possible is essential for project success.

It is the intent and purpose of PREDICT and the USAID EPT to make data as widely and freely available as possible; that said, it is essential that information sharing is accomplished without sacrificing confidentiality and intellectual propriety.

Zoonotic disease surveillance data must be shared with local, state, and national animal and human health authorities at the earliest opportunity so that, as appropriate, authorities can act on the information to institute disease prevention and control measures, and can develop and disseminate accurate and timely risk communication messages to the public and other key audiences.

PREDICT recognizes that in some situations, PREDICT partners will not be the legal "owners" of samples, as some governments retain ownership of all samples from humans, livestock and wildlife acquired in that country. In these situations, neither the PREDICT submitter(s) nor the laboratory can legally claim samples as their property. In these situations, intellectual property rights to discoveries in those samples need to be negotiated.

As the PREDICT project is ongoing, it is a PREDICT policy that all samples collected during the project will remain in the possession of the PREDICT submitter (and may be stored by the partner lab as defined in section IV), or if loaned out for collaborative research activities, be returned to the PREDICT submitter or laboratory for storage as soon as possible.

Section 2.1.4. Definitions

- ***PREDICT***: Consortium among the University of California, Davis, Metabiota, Inc., Wildlife Conservation Society, EcoHealth Alliance, and the Smithsonian Institution.

- ***PREDICT Submitter:*** A member of the PREDICT consortium (above) or the partner of the consortium which submitted, or organized submission of the sample for pathogen discovery. At the discretion of the PREDICT consortium partner, subawardees may jointly or solely submit samples, and thus retain a share of IP.

- ***PREDICT Partner lab:*** A diagnostic laboratory that regularly receives PREDICT funds (i.e., a subawardee) to participate in the PREDICT project on an ongoing basis, conducting PREDICT diagnostics or advanced molecular characterization. Examples include Columbia University and Institut Pasteur du Cambodge, and those designated as regional or in-country pathogen detection and discovery labs (including government and national research laboratories).

- ***PREDICT lab data***: Data, including test results, sequences and isolates generated by any laboratory from PREDICT samples, and pooled data prepared for joint analysis to meet PREDICT objectives.

- ***PREDICT publications***: Publications and presentations derived from unpublished PREDICT lab, field, and other analytical data, as well as PREDICT-generated and -specific methodologies and protocols.

Section 2.1.5. Guidelines for Sample Submission and Data Sharing

Section 2.1.5a. PREDICT Sample Submission to Commercial Laboratories

Biological samples (e.g. blood, sera, plasma, urine, swabs, tissues) collected by PREDICT may be submitted to commercial (i.e. fee-for-service) diagnostic laboratories to test for pathogen exposure or detection.

The results, including lab data, sequences, and nucleic acid products, shall be the shared intellectual property of:

1st: the PREDICT submitter(s); and
2nd: the outside researcher or program that obtained the sample (if applicable, and except as otherwise specified in Section III).

The PREDICT submitter(s) shall retain ownership of any remaining sample or untested samples not utilized for PREDICT testing; it is the responsibility of the submitter(s) to arrange for return of remaining samples from the laboratory in a timely manner.

As is customary, the commercial laboratory will provide testing results to the client (PREDICT submitter(s)) only.

Posting and publication of test result and sequence (including submission to the Genbank database) data resulting from analysis conducted by a commercial laboratory are the sole responsibility and provenance of the PREDICT submitter(s) (see Section VII). The PREDICT submitter(s) shall duly identify/acknowledge the diagnostic laboratory for its service in all reports and publications.

Section 2.1.5b. PREDICT Sample Submission to Outside (Non-PREDICT) Research Laboratories (Non-Commercial, Non-Fee-for-Service), Including Laboratories at Academic, Governmental, or Private Institutions

Biological samples collected by PREDICT may be submitted to a research laboratory that is not a regular PREDICT Partner Laboratory (as defined above) to test for pathogen exposure or detection as part of a research collaboration.

The samples are wholly the property of the PREDICT submitter(s) (except as specified in Section III).

The PREDICT submitter(s) shall retain ownership of any remaining sample not utilized for PREDICT testing; it is the responsibility of the submitter(s) to arrange for return of remaining samples from the laboratory in a timely manner.

The results, including lab data, sequences, and nucleic acid products, shall be the shared intellectual property of:

1st: the PREDICT submitter(s); and
2nd: the research laboratory; and
3rd: the outside researcher or program that obtained the sample (if applicable, and except as otherwise specified in Section III).

The research laboratory shall immediately and only report test results and sequence data to the PREDICT submitter(s). The submitter(s) shall be responsible for entering the data into the EIDITH database, and for disseminating results to the PREDICT Executive Committee and to research or program partners (as applicable).

The PREDICT submitter(s) shall have the first right of refusal of first- and last- authorship on all data resulting from the submission of PREDICT samples if the planned paper's primary focus is not on the diagnostic or laboratory techniques. Decision-making regarding publication of data resulting from submission of samples to a research laboratory by PREDICT shall be between the PREDICT submitter(s) and the research laboratory (see Section VI). Authorship decisions should be based on a reasonable and honest assessment by the parties of each parties' intellectual contributions to the publication.

Parties may jointly sign and date this section of this document to indicate that they have read and are willing and able to comply with PREDICT's policies for biological sample submission, data-sharing, and authorship of scientific papers.

PREDICT Submitter:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Collaborating Laboratory:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Section 2.1.5c. PREDICT Sample Submission to PREDICT Partner Laboratories

Biological samples submitted by a PREDICT submitter(s) to PREDICT partner laboratories (as defined above) become the joint property of the PREDICT submitter(s) and the partner laboratory, except as otherwise specified in Section III.

Partner laboratories may perform PREDICT diagnostics as well as advanced pathogen detection diagnostic analyses and provide diagnostic support to PREDICT partners in a region on a non-fee- for-service basis.

Results, including lab data, sequences, and nucleic acid products, are the shared intellectual property of the PREDICT submitter(s) and the partner lab, except as otherwise specified in Section III.

All test result and sequence data generated by the partner laboratories on samples submitted by PREDICT shall immediately be made available by the partner laboratories to the PREDICT submitter(s). These data will immediately be posted to the EIDITH database. The PREDICT submitter(s) is responsible for disseminating results to the PREDICT Executive Committee and other researchers who may have contributed to sample acquisition, as applicable and appropriate.

The PREDICT submitter(s) shall have the right of first refusal of first- and last- authorship on all data resulting from the submission of PREDICT samples to the partner laboratories for pathogen exposure, detection and/or discovery if the planned paper's primary focus is not on the diagnostic or laboratory techniques. In some cases, it may be appropriate for the PREDICT submitter(s) to be 'joint first author' with the partner laboratory's pathogen discovery lead. Likewise, joint last- authorship is an option for the senior person from PREDICT and the partner laboratory. Authorship decisions should be based on a reasonable and honest assessment by the parties of each party's intellectual contributions to the publication.

If an authorship decision is in dispute, the authors shall appeal to the PREDICT Executive Board, which will make a final and binding decision regarding authorship order.

Parties may jointly sign and date this section of this document to indicate that they have read and are willing and able to comply with PREDICT's policies for biological sample submission and data- sharing, and authorship of scientific papers.

PREDICT Submitter:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

PREDICT Partner Laboratory:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Section 2.1.6. PREDICT Sample Acquisition from Other Researchers/Programs

In order to meet PREDICT objectives, PREDICT may request access to a portion of human and animal biological samples collected by other researchers or programs noting that the appropriate authority must be consulted, which in most cases is the Principal Investigator of the project, and may include the government of the country in which the samples have been collected.

Sharing a portion of collected samples with PREDICT is wholly the decision of the researcher or program.

If the researcher or program agrees to provide samples to PREDICT, the samples become the joint property of the researcher/program and the PREDICT submitter(s) (except as otherwise specified in Section III).

In agreeing to provide a portion of collected samples to PREDICT for pathogen detection or discovery, the researcher or program gives implicit permission to PREDICT to submit the samples for testing to a diagnostic laboratory of the PREDICT submitter(s)' choosing.

The results, including lab data, sequences, and nucleic acid products resulting from all PREDICT analyses of the samples are the shared intellectual property of:

1st: the PREDICT submitter(s); and the researcher/program that originally obtained the sample

2nd: the research laboratory that performed the diagnostics (as applicable, and except as otherwise specified in Section III)

Dissemination of test result and sequence data resulting from PREDICT sample analysis is the sole responsibility and provenance of the PREDICT submitter(s). The PREDICT submitter(s) is responsible for posting the data to the EIDITH database, and for disseminating results to the researcher/program that obtained the sample.

The PREDICT submitter(s) shall have first right of refusal of first- and last-authorship rights on publications resulting from submission of shared samples to diagnostic laboratories for PREDICT. That said, decision-making regarding publication of data resulting from submission of samples acquired from outside researchers or programs shall be made jointly by the PREDICT submitter(s) and the researcher (and the research laboratory, as applicable; see Section IV).

If an authorship decision is in dispute, the authors will refer the issue to the PREDICT Executive Board, which will consider the problem and provide guidance regarding joint publication of PREDICT-derived data.

Parties may jointly sign and date sections or the entirety of this document to indicate that they have read and are willing and able to comply with PREDICT's policies for biological sample acquisition from outside (non-PREDICT) researchers and programs.

PREDICT Submitter:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Collaborating Partner:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Section 2.1.7. PREDICT Global-level Publications

PREDICT shall prioritize collaborative publications of PREDICT data that have been pooled and analyzed in ways that serve and meet PREDICT objectives.

That said, individual PREDICT partners are encouraged to present and publish results based on their own data, if and only if such presentations and publications do not pre-empt or undermine the scientific value and contribution of a PREDICT collaborative publication.

In order to do so, individual PREDICT partners (the first author) must submit a publication proposal to the PREDICT Executive Board (EB), including (but not limited to) the following information:

- Working title for manuscript
- List of authors and affiliations

The EB will review publication proposals on a regular basis and suggest ways to avoid overlap among proposed papers, by combining authorship for essentially identical work, or to better define papers to reduce overlap with others. Authorship decisions should be based on a reasonable and honest assessment by the parties of each parties' intellectual contributions to the publication.

If an authorship decision is in dispute, the authors will refer the issue to the PREDICT Executive Board, which will consider the problem and provide guidance regarding joint publication of PREDICT-derived data.

PREDICT Submitter:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Collaborating Partner:

Name: _____ Institution/Organization: _____

Signature: _____ Date: _____

Section 2.2. PREDICT Public Data Release Plan

Prepared by
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and the PREDICT One Health Consortium

This document was made possible by the generous support of the American people through the United States Agency for International Development (USAID) Emerging Pandemic Threats PREDICT. The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

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Suggested Citation Form: PREDICT One Health Consortium 2016. PREDICT Operating Procedures: PREDICT Public Data Release Plan.
FEBRUARY 4, 2016

PREDICT, a project of USAID's Emerging Pandemic Threats Program, is supporting global early warning capacity to detect and reduce the impacts of emerging diseases that move between wildlife and people (zoonotic diseases). Access to accurate, comprehensive, and timely surveillance data is critical to predicting and responding to emerging diseases of wildlife origin. *Our basic premise is that there should be no barriers to access to the data necessary for effective disease control and public health measures*. This document outlines how data will be shared within the PREDICT consortium, our partners, stakeholders, the scientific community, and the general public.

Data sharing actions must at all times be consistent with obligations to, and agreements with, government agencies (e.g., Ministries of Health, Agriculture, and the Environment) of the host countries in which we work. Furthermore, this policy is subject to the World Health Organization International Health Regulations (http://www.who.int/ihr/en/). Finally, public data release is subject to the privacy measures outlined in the "EIDITH Policy Surrounding the Protection of Privacy of Sample Providers".

This plan pertains specifically to field surveillance and test result data (i.e., data resulting from sampling and diagnostic testing of wildlife, domestic animals as needed, and humans in select countries) and may include information on animal-human interfaces as well as behaviors and practices. Digital surveillance is derived from public data sources, and therefore is not subject to this policy.

Data resulting from disease outbreak or mortality events is treated separately from routine surveillance data, given the different levels of urgency associated with sharing of these data.

Effectively providing surveillance data for disease control and prevention involves a number of steps that need to occur before data is useful for in-country governments to take action. These steps include:

- Collecting samples
- Transporting samples to laboratories for testing
- Conducting preliminary screening tests to identify presumptive positives
- Conducting additional tests on presumptive positives to confirm results

Therefore, there will always be a time lag between collection of data and the ability to share meaningful results. Until the time that confirmed laboratory results are available for sharing with in-country governments, the PREDICT Country Coordinator (in consultation with designated Points of Contact on the PREDICT Global Diagnostics and Data Management teams) will regularly (at least quarterly for routine surveillance activities) provide updates to in-country government contacts and USAID to include:

- number of animal sampled to date
- number of samples collected to date

- number of samples collected to date for which initial testing has started
- number of samples collected to date for which at least one final (i.e. confirmed) test result is available
- estimated timeframe for completing the testing of the remaining samples

The process for sharing confirmed laboratory results and other associated data is described below in greater detail.

PREDICT Test Result Public Release

Rapid Public Release of Data

All data are examined at entry and later upon integration into the system, for completeness, accuracy, and logical consistency. Once all test results (e.g., initial detection by PCR and subsequent sequencing of viruses) are available for a given specimen, the results are interpreted in light of all available scientific literature and previous PREDICT findings by PREDICT virologists. This iterative process ensures the highest quality, most robust, data possible. After this process of examination and interpretation is complete, data are provided to host governments in written form for examination and discussion with PREDICT staff. Host governments, after review, approve data for public, typically within 12 weeks of data collection. Data are then released through the PREDICT public site: www.healthmap.org/predict (e.g., Figure 1).

Figure 1: Screenshot of the PREDICT public website illustrating release of data to general public, www.healthmap.org/predict.

Distribution of PREDICT Viral Sequences

In order to balance host country and researcher scientific publication goals and greater societal benefits of sharing sequences, the process for distributing specific nucleic acid sequences is as follows:

1. After interpretation, sequences are made available to host country governments immediately upon request. Unless otherwise restricted by those governments, sequences will also be available upon request to other international health organizations, including USAID.
2. Upon approval of data release by the host country governments, sequences are submitted to Genbank in batches on an ongoing basis. Depending on requests from host country governments or sample collectors, a temporary hold on public dissemination from GenBank may be requested if needed.
3. If a temporary hold is placed on sequence data release through GenBank, sequence availability will coincide with inclusion of the sequences in a publication (i.e., sequences included in publications will be released to the public at the time of publication).
4. If there are no plans by the host country government or PREDICT consortium to include the sequences in a publication, the sequences will automatically be released to the public upon submission to GenBank. If a temporary hold has been placed but no publication includes the sequence within two years of submission to GenBank, the sequences will automatically be released to the public.

Given that the sequences will be uploaded to GenBank in batches once they have been interpreted, in an emergency, data release can proceed immediately (without upload delays).

Section 2.2.1. Final Confirmed Diagnostic Test Results from Routine Surveillance (S)

Please note that: 1) these release levels could happen simultaneously, e.g., S3 and S4 could occur at the same time; and 2) the timelines are maximum limits: release can occur before the specified limit.

Release Level	Accessible To	Means of Distribution	Timeline (From receipt of confirmed results)
S1	Country coordinator, regional epidemiologist, diagnostic laboratory team lead, Executive Board	Email, restricted local databases, EIDITH	Within 2 weeks
S2	In-country government contacts	Informal and/or formal briefings	At least quarterly
S3	(Test Results) General public (aggregated data), USAID, PREDICT consortium, PREDICT partners, scientific community	Email, informal and formal briefings and meetings, quarterly reports, EIDITH (to PREDICT consortium only), scientific publications, http://data.preditct.global	After data are released by government
S4	(Sequence data) General public, USAID, PREDICT consortium, PREDICT partners, scientific community	GenBank	Upon submission to GenBank with approval of sequence release from the sample collector and host country government or scientific publication – whichever occurs first (may vary depending on scientific publication requirements but will not exceed two years from aggregated data release and submission to GenBank).

Section 2.2.2. Final Confirmed Diagnostic Results Associated with an Outbreak (O) or Mortality Event

Exceptions will be made when sharing of data is necessary to protect public health, in consultation with host-country governments and international organizations. Please note that the timelines are maximum limits; release can occur before the specified time limit.

Level	Accessible To	Means of Distribution	Timeline (From receipt of confirmed results)
O1	In-country government contacts, Country coordinator, regional epidemiologist, diagnostic laboratory team lead, Executive Board	Email, restricted local databases, informal and formal briefings, EIDITH	ASAP
O2	(Test Results) USAID, PREDICT consortium, PREDICT Partners, scientific public, general public (aggregated data), likely via ProMed (summary data)	Email, informal and formal briefings, risk information sheets and strategic communications, quarterly reports, scientific publications, EIDITH (to PREDICT consortium only) public distribution through http://data.predict.global, ProMED-Mail	As specified by IHR or as soon as messages are developed in-conjunction with host country government (expected immediately in outbreak situations but should not exceed 12 weeks)
O3	(Sequence data) General public (aggregated data), USAID, PREDICT consortium, PREDICT partners, scientific community	GenBank	As specified by IHR or upon approval of sequence release from the sample collector and host country government or scientific publication – whichever occurs first (expected very soon after summary data release; may vary depending on situation).

Section 2.3. EIDITH Policy Surrounding the Protection of Privacy of Sample Providers

Prepared by
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Email: predict@ucdavis.edu.

Suggested Citation Form: PREDICT One Health Consortium 2016. PREDICT Operating Procedures: EIDITH Policy Surrounding the Protection of Privacy of Sample Providers.

FEBRUARY 4, 2016

During implementation of the PREDICT project, surveillance samples may be collected from live or dead wildlife in the possession of hunters, animal traders, farmers, animal control/enforcement officers and others who work closely with animals and/or wild and domestic animal management (hereafter called 'sample providers'), and from domestic animals and people. PREDICT is adhering to the following multistep process to ensure the privacy of sample providers.

- **Overview:** PREDICT takes a conservative position regarding protection of participants' privacy, to ensure that breaches of confidentiality are either averted entirely or will present no greater harm than is presented in the everyday life of a hunter, animal trader, farmer, animal health worker, or other person whose contact with animals falls under the scope of this study. Our practices take into account that the "everyday risk" faced by our sample providers varies by country, location and profession, particularly in the areas of wildlife hunting and trade, where legal and illegal activities may be occurring concurrently in a location.
- **EIDITH:** PREDICT will utilize a secure, password-protected centralized database (the Emerging Infectious Disease Information Technology Hub, EIDITH) to store data for access by the PREDICT consortium only for surveillance data analysis. The EIDITH database is maintained by the PREDICT information management team. There will be no public access to the EIDITH database.
- **Personal Information:** No personal information (names, addresses or other means to identify individuals) will be recorded in EIDITH.
- **Data collection:** Data about wildlife surveillance samples (e.g., species, age, location, etc.) will be collected by field workers and recorded on an electronic form, and submitted to the PREDICT information management team for entering into the EIDITH database. The form will not have fields for personal information about the sample provider.
- **Public Data Release:** Subject to local laws and agreements made with government agencies, PREDICT will not publicly release data on the geographic location of sampling events to a level of precision that allows third parties to deduce the sample provider's identity based on the released location information. The PREDICT Information Management Coordinator, in discussion with the PREDICT Country Coordinator, will determine the appropriate scale (e.g., district, province) at which to report the data that is sufficiently protective of privacy so as to prevent third party deduction of the sample provider's identity.
- **Disease Notification:** PREDICT must balance the need to protect the privacy of a sample provider with national and international obligations and rules regarding pathogen reporting. Following local laws and agreements with government agencies in the countries where we work, if PREDICT confirms the presence of a pathogen considered a risk to public or livestock health in samples collected in a specific location, PREDICT will notify appropriate government animal and human health

agencies of the outbreak location so that governments may take appropriate action to protect local populations according to their established procedures and laws. As personal information is not stored in EIDITH, no personal identities can or will be revealed as part of this process. The ***PREDICT Public Data Release Plan*** has more details on public data release.

Section 2.4. Environmental Mitigation and Monitoring Plan

Prepared by
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This document was made possible by the generous support of the American people through the United States Agency for International Development (USAID) Emerging Pandemic Threats PREDICT. The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

Email: predict@ucdavis.edu.

Suggested Citation Form: PREDICT One Health Consortium 2016. PREDICT Operating Procedures: Environmental Mitigation and Monitoring Plan

Section 2.4.1 Environmental Mitigation and Monitoring Plan – Global & All Country Levels

IEE Activity 1: Procurement, storage, management, and disposal of public health commodities			
IEE Conditions	**Mitigation Measures**	**Monitoring Measures**	**Timing and Responsible Parties**
1) UCD and collaborating partners will store products according to MSDS guidelines with disposal of all products and expired commodities conducted in coordination with manufacturer or in compliance with WHO[1], EGSSAA[2], and PREDICT guidelines[3]; as appropriate. 2) UCD and all collaborating partners will work with the host country as appropriate on aspects of essential medicine supply chain management, including estimating demand, distribution, and storage issues of time and temperature. 3) UCD and all collaborating partners will treat packaging and disposal of all public health commodities using guidelines provided by PREDICT (Biosafety and PPE Use, Implementing a Cold Chain for Safe Sample Transport and Storage), and EGSSAA (Ch. 15: Solid Waste).	1) Provide and maintain product MSDS sheets and ensure products are stored and disposed of according to manufacturer guidelines or in compliance with all WHO, EGSSAA, and PREDICT guidelines as appropriate; ensure personnel have reviewed protocols prior to handling materials. 2) Provide PREDICT guidelines and conduct trainings on cold chain and supply chain management and provide documentation that all recommended measures are implemented. 3) Provide PREDICT and EGSSAA guidelines and conduct trainings on disposal of all public health commodities; ensure personnel have reviewed protocols prior to handling materials; provide documentation of trainings and implementation of guidelines.	• Regular inspection of training records and signed safety sheets, and periodic site visits to ensure proper implementation of supply inventory, storage, and disposal practices and implementation of all guidelines and protocols at all facilities and sites. • Documentation received and reviewed by UCD for compliance at all sites.	Semiannual site visits from operational team representatives with regular oversight of all sites and facilities at the country level by Country Coordinators. Proper documentation will be maintained by each country office. Reporting will be included in the annual project report to USAID. **Responsible Parties:** *Global:* Dr. Jonna AK Mazet (PREDICT Global Director) and cognizant USAID AOR *Country:* Country Coordinators

[1] WHO *Guidelines for Safe Disposal of Unwanted Pharmaceuticals During and After Emergencies,* available online at www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

[2] Environmental Guidelines for Small-Scale Activities in Africa (EGSSAA, 2nd Ediciton, Chapter 15) available online at http://www.encapafrica.org/EGSSAA/Word_English/solidwaste.doc

[3] USAID PREDICT project protocols for safe animal capture, handling, sampling and packing and shipping samples available online at http://www.vetmed.ucdavis.edu/ohi/predict/predict_publications.cfm#Protocols

IEE Activity 2: Generation, storage, handling, and disposal of hazardous or highly hazardous medical waste			
IEE Conditions	**Mitigation Measures**	**Monitoring Measures**	**Timing and Responsible Parties**
1) UCD and collaborating partners will include training in procedures to properly handle, label, treat, store, transport, and dispose of blood, sharps, and other medical waste, as applicable, following either WHO or EGSSAA guidelines (Ch. 8: Healthcare Waste: Generation, Handling, Treatment and Disposal) and consistent with national policy and procedures for medical waste. 2) UCD and all collaborating partners (in coordination with AORs) will assure that, to the extent possible, all implementing partners have adequate procedures and capacities in place at facilities directly providing services to properly handle, label, treat, store, transport, and dispose of blood, sharps, and other medical waste. 3) UCD and all collaborating partners will implement best practices for the safe handling, storage, and transportation of healthcare waste following PREDICT (Safety Guide: Laboratory Operations) EGSSAA (Ch. 8: Healthcare Waste: Generation, Handling, Treatment and Disposal), or WHO (Safe Management of Wastes from Health Care Activities) guidelines as appropriate.	1) Provide and maintain documentation that all medical waste is stored and disposed of according to manufacturer guidelines or in compliance with all WHO, EGSSAA, and PREDICT guidelines as appropriate; ensure personnel have reviewed appropriate protocols prior to handling materials. 2) Provide PREDICT guidelines to all facilities and conduct trainings for all implementing personnel in handling of sharps and in the generation and disposal of hazardous or highly hazardous medical waste and provide documentation that all recommended measures are implemented; complete the *Healthcare Waste Management Minimum Program Checklist and Action Plan* annually. 3) Provide PREDICT, EGSSAA, and WHO guidelines and conduct trainings in handling of sharps and in the generation and disposal of hazardous or highly hazardous medical waste; assure personnel have reviewed protocols prior to handling and disposing of materials; provide documentation of trainings and implementation of guidelines.	• Regular inspection of training records and training certifications on file for all personnel involved in the handling, generation, and disposal of hazardous materials and medical waste; regular inspection of signed safety sheets. • Periodic site visits and interviews with staff at implementing facilities and sites to ensure proper implementation of hazardous material handling, storage, and disposal guidelines and protocols.	Semiannual site visits from operational team representatives with regular oversight of all sites and facilities at the country level by Country Coordinators. Proper documentation will be maintained by each country office. Reporting will be included in the annual project report to USAID. **Responsible Parties:** *Global:* Dr. Jonna AK Mazet (PREDICT Global Director) and cognizant USAID AOR *Country:* Country Coordinators

IEE Activity 3: Establishing animal and human viral surveillance capacity in selected countries and regions			
IEE Conditions	**Mitigation Measures**	**Monitoring Measures**	**Timing and Responsible Parties**
1) UCD and collaborating partners will conduct sampling in a humane and ethical manner, including practicing a "no kill policy" for animals as possible. 2) UCD and all collaborating partners will assure proper training and management of sampling activities and will follow the USAID/PREDICT protocols and IRB and IACUC ethical guidelines as appropriate (e.g. Safe Animal Capture and Sampling, Small Carnivore, Bat, Rodent, Primate, Livestock and other taxa Sampling Methods, Bushmeat Sampling Methods, Sampling Methods, Packing and Shipping Biological Material). 3) UCD and all collaborating partners will follow all country specific laws and regulations with regards to human sampling and animal capture, handling, and sample acquisition.	1) Provide compliance with approved PREDICT and UC Davis Institute for Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) protocols, as well as country-level ethical approvals; provide and maintain documentation that all appropriate project personnel have received IRB and IACUC 101 training and training in PREDICT ethical and safe sampling and animal handling protocols. 2) Provide PREDICT guidelines and protocols and conduct trainings in humane, ethical, and biologically safe human sampling and animal capture, handling, and sample acquisition. 3) Provide and maintain documentation of all country specific permissions for conduct of human sampling and animal capture, handling, and sample acquisition.	• Regular inspection of training records, and training certifications on file for all personnel involved in the handling and sampling of people and animals; annual reporting to IRBs and IACUC through the UC Davis systems and in compliance with local requirements. • Procedures for safe and ethical conduct of human sampling and animal capture, handling, and sample acquisition included in appropriate training materials. • Provide documentation of all country specific permissions; regular inspection of records of ethical and legal permissions for sampling.	Oversight provided by Country Coordinators. Proper documentation will be maintained by each country office. Reporting will be included in the annual project report to USAID with additional reporting on an annual basis through the internal UC Davis IRB and IACUC tracking systems and country-level procedures. **Responsible Parties:** *Global:* Dr. Jonna AK Mazet (PREDICT Global Director) and cognizant USAID AOR *Country:* Country Coordinators

IEE Activity 4: Outbreak response planning and implementation			
IEE Conditions	**Mitigation Measures**	**Monitoring Measures**	**Timing and Responsible Parties**
1) UCD and collaborating partners will coordinate with local environmental experts, officials, NGOs, and the MEO to understand sensitive species and habitats in the region and to design procedures in outbreak response and support activities that ensure their protection. 2) UCD and all collaborating partners will ensure that trained personnel can visually identify important habitat or species in outbreak support and response plans. 3) UCD and all collaborating partners will provide training in and will implement best practices for the solid waste management in outbreak situations following PREDICT guidelines or the Sphere Handbook[4], as appropriate.	1) Meet with local environmental experts, officials, NGOs, and the MEO and discuss outbreak planning with regards to sensitive species and habitats in the region; include sensitivity training for environmental impacts and outbreak response in training materials. 2) Provide trainings for staff and ensure personnel have reviewed protocols prior to outbreak responses. 3) Provide PREDICT, EGSSAA, and Sphere Handbook guidelines and conduct trainings on management and disposal of solid and medical waste in outbreak situations; ensure personnel have reviewed protocols prior to handling materials; provide documentation of trainings and implementation of guidelines.	• Interview staff to confirm meetings have been conducted with local experts; review of response plans, as available, to ensure environmental impact has been considered in their design. • Regular inspection of training records and outbreak response plans (as appropriate). • Periodic site visits with staff interviews to ensure proper implementation of all guidelines and protocols for the management and disposal of solid and medical waste.	Oversight of records at the country level by Country Coordinators with review of response plans by operational leads. Proper documentation will be maintained by each country office. Reporting (as appropriate) will be included in the annual project report to USAID. **Responsible Parties:** *Global:* Dr. Jonna AK Mazet (PREDICT Global Director) and cognizant USAID AOR *Country:* Country Coordinators

[4] *Sphere Handbook*, available online at: www.spherehandbook.org/en/solid-waste-management-standard-1-colleciton-and-disposal

Narrative of Mitigation Plan

As implementing partner for PREDICT 2, UC Davis will use annual Environmental Mitigation and Monitoring Reports (EMMR) to ensure programmatic compliance with 22 CFR 216 and ADS 204.5.4 by documenting that the conditions specified in the IEE have been met for all activities carried out under PREDICT 2. We will coordinate and communicate with Mission Environmental Officers (MEOs) in each host country, to ensure maximum awareness of host country environmental laws and regulations and enable best practices for compliance. All mitigation and monitoring procedures below apply to all regions and countries; no exceptions or changes in procedures are deemed necessary for successful implementation of the plan.

1. Procurement, storage, management, and disposal of public health commodities

Mitigation: All public health commodities including test kits and pharmaceuticals will be handled safely in accordance with the manufacturer's Materials Safety Data Sheet (MSDS) when applicable. Expired or spoiled pharmaceuticals will be disposed, to the extent feasible, in accordance with the guidelines at: www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf. Packing and disposal of other public health commodities will be treated using the PREDICT guidelines for "Biosafety and PPE Use" and "Implementing a Cold Chain for Safe Sample Transport and Storage", and the "Environmental Guidelines for Small-Scale Activities in Africa (EGSSAA) 2nd Edition, Chapter 15: Solid Waste" (http://www.encapafrica.org/EGSSAA/Word_English/solidwaste.doc)

Monitoring Indicator & Method: The country coordinator will ensure all personnel are trained in handling and disposal of public health commodities and will maintain and inspect training records during periodic site visits, with additional oversight through periodic site visits provided by operational leads. Personnel will be required to review and sign a safety review sheet prior to handling public health commodities (materials, test kits, and pharmaceuticals) that may pose a health risk. During site visits and through interviews, operational lead and/or the country coordinator as appropriate will confirm all personnel have reviewed safety review sheets prior to their handling commodities that may pose a health risk, will inspect and confirm that all commodities are stored in accordance with the manufacturer's recommendation if applicable, and that all commodities and solid waste is disposed of according to recommended guidelines.

2. Generation, storage, handling and disposal of hazardous or highly hazardous medical waste

Mitigation: Blood, other biological materials, sharps, and infectious waste generated at trainings for health professionals, from surveillance field sampling activities, and from laboratory activities will be handled in accordance with WHO guidelines "Environmental Guidelines for Small Scale Activities in Africa, Chapter 8", EGSAA Chapter 8 "Healthcare Waste: Generation, Handling, Treatment and Disposal" (http://www.encapafrica.org/EGSSAA/Word_English/medwaste.doc), and the PREDICT "Safety Guide to Laboratory Operations" consistent with national policy and procedures for medical wastes. Sharps will be collected in puncture-proof containers. Highly infectious waste will be immediately sterilized. On site collection of waste will be handled

frequently and stored appropriately for safe handling and disposal. All trainings that involve the use of sharps or infectious materials will include a safety review regarding the safe handling and disposal of these materials. All surveillance and laboratory personnel involved in activities that may include handling sharps or infectious waste will be required to review and sign a safety procedures sheet prior to participating in such activities.

Monitoring Indicator & Method: Training materials will contain lessons on safe handling and disposal of sharps and infectious waste. The country coordinator will ensure all personnel are trained in handling and disposal of public health commodities and will maintain and inspect training records during periodic site visits, with additional oversight through periodic site visits provided by operational leads. In addition, during site visits and through interviews (to the extent practical), the country coordinator will confirm that all personnel and trainees are appropriately trained regarding the safe handling and disposal of sharps and infectious waste, and that sharps and infectious waste are properly disposed following PREDICT trainings and field sampling activities. Country coordinators will complete the "Healthcare Waste Management Minimum Program Checklist and Action Plan" for all facilities directly engaged in implementation of project activities involved in generation of sharps and infectious waste.

3. Establishing animal and human surveillance capacity in selected countries and regions

Mitigation: Personnel will review safety procedures prior to activities that involve sampling people or handling animals. Training materials related to sampling people and animals will include a safety review. UC Davis Institutional Review Board (IRB)* and Institutional Animal Care and Use Committee** (IACUC) approved protocols will be obtained for all sampling activities, as will all required local ethical approvals. The IRBs and IACUCs require strict standards to ensure the safety of people and animals and to protect information used in research or training. The required permits will be obtained from the appropriate national authorities prior to collecting samples. If surveillance activities require handling threatened or endangered species, the appropriate special permits will be obtained. PREDICT does not anticipate any activities that will impact wildlife habitats. All training and management of sampling activities will follow PREDICT-generated protocols and guidelines including "***Safe Animal Capture and Sampling***", "***Small Carnivore Sampling Methods***", "***Bushmeat Sampling Methods***", "***Bat Sampling Methods***", "***Rodent Sampling Methods***", "***Non-Human Primate Sampling Methods***", "***Packing and Shipping Biological Samples***" and others where relevant and appropriate.

**The UC Davis IRB Administration is committed to following the federal regulations to protect the rights and welfare of human subjects involved in research conducted under the auspices of the University of California, Davis. All four UC Davis IRB administration committees fall under the UC Davis Federalwide Assurance with the US Department of Health and Human Services/Office of Human Research Protections (DHHS/ORRP). The function of the IRB committees is to ensure adherence to all federal, state, local and institutional regulations covering the protection of human subjects in research. IRB review is required for both funded and non-funded human*

subjects research. UC Davis has also adopted a Human Research Protection Program Plan to outline responsibilities to the UC Davis research community.

***IACUC is charged with implementing the UC Davis Policy on the Care and Use of Animals in Teaching and Research. This policy provides that University practices for the procurement, housing, and care and use of animals must conform to: 1) the ILAR Guide for the Care and Use of Laboratory Animals; 2) the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching; 3) all regulations of the United States Department of Agriculture (USDA) issued by the USDA implementing the Animal Welfare Act (AWA) of 1966 and its amendments (9 CFR, Chapter 3); and 4) the Public Health Service's Policy on Humane Care and Use of Laboratory Animals.*

Monitoring Indicator & Method: Safe procedures will be reviewed prior to fieldwork involving the human sampling and handling of animals. Under direction of the country coordinators and operational leads as appropriate, lead field staff will review relevant IRB and IACUC protocols and permits prior to fieldwork. Handling procedures are detailed in PREDICT training materials and cover safe and ethical handling/sampling, biosafety and use of PPE, decontamination procedures, and safe disposal of contaminated PPE and other materials to ensure adherence for protection of human and animal health in all activities. Country coordinators will confirm lead field staff have reviewed the relevant protocols and permits and will monitor the field activities for compliance. In addition, the country coordinator will maintain and inspect training records and county regulatory documents to ensure compliance with all relevant country specific laws and regulations. Annually, reports will be submitted on the numbers of people and animals sampled through the IRB and IACUC tracking systems, including any "accidental take" of threatened or endangered species.

4. Outbreak response planning and implementation

Mitigation: Upon invitation by host country governments, PREDICT engagement in outbreak response support and the provision of technical assistance will be conducted in a manner consistent with all guidelines for safe handling, management, and disposal of commodities, sharps, and infectious waste and in compliance with IRB and IACUC protocol and PREDICT guidelines as appropriate and under supervision of the outbreak task force and host country government partners. PREDICT will coordinate with local environmental experts, officials, NGOs, and the MEO to design procedures to ensure protection of any sensitive habitat and species during outbreak activities and will ensure that all project personnel engaged in response efforts are trained to visually recognize important habitat and sensitive species.

Monitoring Indicator & Method: Training materials will contain lessons on safe handling and disposal of sharps and infectious waste. During periodic site visits and through interviews, the country coordinator and/or operational leads as appropriate, will confirm that all personnel and trainees are appropriately trained regarding the safe handling and disposal of sharps and infectious waste, and that to the extent practical, sharps and infectious waste are properly

disposed during outbreak response activities. Staff will review relevant IRB and IACUC protocols and permits prior to response activities. Training materials will cover safe and ethical handling/sampling of people, protected data, and animals; biosafety and use of PPE; decontamination procedures; and safe disposal of contaminated PPE and other materials to ensure adherence for protection of human, animal, and environmental health in outbreak situations. During periodic site visits and through interviews, country coordinators will confirm lead field staff reviewed the relevant protocols and permits and will monitor the response activities for compliance. Country coordinators will work with local environmental experts (if not part of current implementation teams) to ensure environmental impact has been considered in design of any response plans and that all response teams providing support or technical assistance during outbreaks have been trained in the recognition of sensitive habitat and species prior to engaging in response efforts and are properly equipped prior to deployment for response efforts. Finally, country coordinators will maintain and inspect training records and conduct interviews with staff to ensure proper implementation of all plans and procedures.

References

[i] WHO *Guidelines for Safe Disposal of Unwanted Pharmaceuticals During and After Emergencies,* available online at www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

[ii] Environmental Guidelines for Small-Scale Activities in Africa (EGSSAA, 2nd Edition, Chapter 15 available online at http://www.encapafrica.org/EGSSAA/Word_English/solidwaste.doc)

[iii] USAID PREDICT project protocols for safe animal capture, handling, sampling and packing and shipping samples available online at http://www.vetmed.ucdavis.edu/ohi/predict/predict_publications.cfm#Protocols

[iv] *Sphere Handbook*, available online at: www.spherehandbook.org/en/solid-waste-management-standard-1-colleciton-and-disposal

Section 2.4.2. Environmental Mitigation and Monitoring Report – Global & All Country Levels

IEE Activity 1: Procurement, storage, management, and disposal of public health commodities			
Mitigation Measures	**Status of Mitigative Measures**	**List any outstanding issues relating to required conditions**	**Remarks**
1) Provide and maintain product MSDS sheets and ensure products are stored and disposed of according to manufacturer guidelines or in compliance with all WHO, EGSSAA, and PREDICT guidelines as appropriate; ensure personnel have reviewed protocols prior to handling materials.			
2) Provide PREDICT guidelines and conduct trainings on cold chain and supply chain management and provide documentation that all recommended measures are implemented.			
3) Provide PREDICT and EGSSAA guidelines and conduct trainings on disposal of all public health commodities; ensure personnel have reviewed protocols prior to handling materials; provide documentation of trainings and implementation of guidelines.			

IEE Activity 2: Generation, storage, handling, and disposal of hazardous or highly hazardous medical waste			
Mitigation Measures	**Status of Mitigative Measures**	**List any outstanding issues relating to required conditions**	**Remarks**
1) Provide and maintain documentation that all medical waste is stored and disposed of according to manufacturer guidelines or in compliance with all WHO, EGSSAA, and PREDICT guidelines as appropriate; ensure personnel have reviewed appropriate protocols prior to handling materials.			
2) Provide PREDICT guidelines to all facilities and conduct trainings for all implementing personnel in handling of sharps and in the generation and disposal of hazardous or highly hazardous medical waste and provide documentation that all recommended measures are implemented; complete the *Healthcare Waste Management Minimum Program Checklist and Action Plan* annually.			
3) Provide PREDICT, EGSSAA, and WHO guidelines and conduct trainings in handling of sharps and in the generation and disposal of hazardous or highly hazardous medical waste; assure personnel have reviewed protocols prior to handling and disposing of materials; provide documentation of trainings and implementation of guidelines.			

IEE Activity 3: Establishing animal and human viral surveillance capacity in selected countries and regions			
Mitigation Measures	**Status of Mitigative Measures**	**List any outstanding issues relating to required conditions**	**Remarks**
1) Provide compliance with approved PREDICT and UC Davis Institute for Animal Care and Use Committee (IACUC)			

and Institutional Review Board (IRB) protocols; as well as country-level ethical approvals; provide and maintain documentation that all appropriate			
IEE Activity 4: Outbreak response planning and implementation			
Mitigation Measures	**Status of Mitigative Measures**	**List any outstanding issues relating to required conditions**	**Remarks**
1) Meet with local environmental experts, officials, NGOS, and the WEO and discuss outbreak planning with regards to sensitive species and habitats in the region, include sensitivity training for environmental impacts and outbreak response in training materials. 2) Provide PREDICT guidelines and protocols and conduct trainings in humane, ethical, and biologically safe human sampling and animal capture, handling, and sample acquisition.			
3) Provide and maintain documentation of all country specific permissions for conduct of human sampling and animal capture, handling, and sample acquisition.			

2) Provide trainings for staff and ensure personnel have reviewed protocols prior to outbreak responses.			
3) Provide PREDICT, EGSSAA, and Sphere Handbook guidelines and conduct trainings on management and disposal of solid and medical waste in outbreak situations; ensure personnel have reviewed protocols prior to handling materials; provide documentation of trainings and implementation of guidelines.			

Section 2.4.3. PREDICT 2 EMMR Annex 1

Table 1: Annex 1. Healthcare waste management minimal program checklist and action plan to be included in training materials/programs.

Elements/Actions	In Place?	Next Steps to be Done		
		What	By Whom	By When
Written plans and procedures				
1. *A written waste management plan* – Describing all the practices for handling, storing, treating, and disposing of hazardous and non-hazardous waste, as well as types of worker training required.				
2. *Internal rules for generation, handling, storage, treatment, and disposal of healthcare waste.*				
3. *Clearly assigned staff responsibilities that cover all steps in the waste management process.*				
4. *Staff waste handling training curricula or a list of topics covered.*				
5. *Waste minimization, reuse, and recycling procedures.*				
Staff Training, Practices, and Protection				
6. *Staff trained in safe handling, storage, Treatment, and disposal.* – Does staff exhibit good hygiene, safe sharps handling, proper use of protective clothing proper packaging and labeling of waste, and sage storage of waste.				
7. *Protective clothing available for workers who move and treat collected infections waste* such as surgical masks and gloves, aprons, and boots.				
8. *Good hygiene practices*. Are soap and, ideally, warm water readily available to workers to use and can workers be observed regularly washing.				
9. *Workers vaccinated* for against viral hepatitis B., tetanus infections, and other endemic infections for which vaccines are available.				
Handling and Storage Practices				
10. *Temporary storage containers and designed storage locations.* 11. Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes?				
12. *Minimization, reuse and recycling procedures.* • Does the facility have good inventory practices for chemicals and pharmaceuticals, i.e.: ○ Use the oldest batch first ○ Open new containers only after the last one is empty; procedures to prevent products from being thrown out during routine cleaning				

13. *A waste segregation system*. • Is general waste separated from infectious/hazardous waste? • Is sharp waste (needles, broken glass, etc.) collected in separate puncture-proof containers? • Are other levels of segregation being applied e.g. hazardous liquids, chemicals and pharmaceuticals, PVC plastic, and materials containing heavy metals (these are valuable, but less essential)?				
14. Temporary storage containers and designated storage locations. • Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes? • Is the location distant from patients or food?				
Treatment Practices				
15. *Frequent removal and treatment of waste* • Are wastes collected daily? • Are wastes treated with a frequency appropriate to the climate and season? ○ Warm season in warm climates within **24 hrs** ○ In the cool season in warm climates within **48 hrs** ○ In the warm season in temperate climates within **48 hrs**				
16. *Treatment mechanisms for hazardous and highly hazardous waste.* (<u>The most important function of treatment is disinfection</u>.) • Are wastes being burned in the open air, in a drum or brick incinerator, or a single-chamber incinerator? • If not are they being buried safely (in a pit with an impermeable plastic or clay lining)? • Is the final disposal site (usually a pit) surrounded by fencing or other materials and in view of the facility to prevent accidental injury or scavenging of syringed and other medical supplies?				
17. Is the waste is transported off-site, are precautions taken to ensure that it is transported and disposed of safely?				

*Training should be conducted before starting activity implementation.

For more detailed checklists and guidance consult: *Safe management of wastes from health-care activities*, edited by A. Prüss, E. Giroult, and P. Rushbrook. Geneva, WHO, 1999, **http://www.who.int/injection_safety/toolbox/docs/en/waste_management.pdf**

Section 2.4.4. PREDICT 2 EMMR Annex 2.

Method	Infectious Waste (laboratory cultures, excreta)	Sharps (needles, blades, broken glass)	Pharmaceutical Waste (expired pharmaceuticals, boxes contaminated by pharmaceuticals)	Chemical Waste (Laboratory reagents, solvents)	Radioactive Waste (unused liquids from laboratory research)
Rotary kiln	✓	✓	✓	✓	✓[2]
Pyrolytic incinerator	✓	✓	✓[1]	✓[1]	✓[2]
Single-chamber incinerator	✓	✓			✓[2]
Drum or brick incinerator	✓	✓			
Chemical disinfection	✓	✓			
Wet thermal treatment	✓	✓			
Microwave irradiation	✓	✓			
Encapsulation		✓	✓	✓[1]	
Safe burial on hospital premises	✓	✓	✓[1]	✓[1]	
Sanitary landfill	✓		✓[1]		
Discharge to sewer			✓[1]		Low-level liquid waste
Inertization			✓		
Other			Return to supplier	Return to supplier	Decay by storage

[1]: Small quantities only
[2]: Low-level infectious waste

Section 2.4.5. Certification

CERTIFICATION

I certify the completeness and the accuracy of the Environmental Monitoring and Mitigation Report (EMMR) compliance monitoring plan for PREDICT 2 COOPERATIVE AGREEMENT above (and covered by the PREDICT 2 PIEE) for which I am responsible:

_____ _____

Signature Date

_____

Print Name

_____

Organization

_____

BELOW THIS LINE FOR USAID USE ONLY

USAID Mission or Central Bureau Clearance of EMMR:

Agreement Officer's Representative: _____ Date: _____

Mission Environmental Officer: _____ Date: _____

Regional Environmental Advisor: _____ Date: _____

Bureau Environmental Officer: _____ Date: _____

Note: If clearance is denied, comments must be provided to applicant.

Section 2.5. Safe Disposal of Carcasses and Infectious Waste Guide

Prepared by
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and the PREDICT One Health Consortium

Objectives: To provide guidelines for the safe transport or disposal of carcasses and potential hazardous infectious waste.

This document was made possible by the generous support of the American people through the United States Agency for International Development (USAID) Emerging Pandemic Threats PREDICT. The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

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Suggested Citation Form: PREDICT One Health Consortium 2016. PREDICT Operating Procedures: Safe Disposal of Carcasses and Infectious Waste Guide.

REV-UC0000303.00040

Table of Contents: Safe Disposal of Carcasses and Infectious Waste

Section 2.5.1. Introduction

Improper disposal of surveillance sampling waste, animal carcasses, and necropsy waste may harm human and animal health and the environment.

Prior to conducting field-sampling activities, plans should be made for safe handling and disposal of all infectious waste materials, necropsy waste and carcasses. Safe handling of infectious materials includes containment, disinfection, local burning, and burial or transport of the materials to a health institution (that has a health care waste incinerator or burial site). The preferred procedure for most field sampling generated waste is to safely contain (i.e., with triple layered protection, see below) and transport the material to a health institution, such as a medical or veterinary facility, that has the capacity to autoclave and incinerate the waste, or has a safe disposal site. There are exceptional circumstances for which the best option may be to dispose of the infectious waste in the field (see recommended procedure for field disposal below).

Carcass disposal is fraught with technical difficulties. Burning – if done properly (i.e., reducing the carcass to ash) is usually done using gasoil (diesel) or wood for fuel. It requires a long time to burn and uses a lot of fuel. In addition, anthrax spores (should they be present) can become airborne if the fire is not managed appropriately. Burial has the advantages of being generally less time-consuming and less expensive, but it does not guarantee destruction of all infectious organisms (e.g., anthrax spores may persist in the soil for decades). Burial also leaves open the possibility that someone could dig up and recover the meat to eat or sell. Or that a scavenger animal could access the carcass. Ultimately the field supervisor must determine the best method for disposal based on the guidance provided below, his/her judgment and resources available.

Section 2.5.2. Collecting and Containing Infectious Materials for Transport

Guidelines for collecting and transporting infectious waste:

1. Use appropriate PPE to handle and move infectious waste – At a minimum, gloves, respirators/masks (N95, N100, or P100), goggles, and an apron or dedicated clothing should be worn when packaging, handling, or moving infectious waste bags or containers. (See ***Section 4. Biosafety and PPE Use*** for more details regarding PPE).
2. Collect infectious waste in strong plastic bags (preferably red or orange colored bags). Bags should not be filled more than ¾ full so they can easily be tied or taped closed without spillage or over stretching the bag. Once sealed, the exterior of the bag should be sprayed with a disinfectant.
3. Use containers with tight lids and secure them on the vehicle – The preferred way to contain bags of infectious waste for transport is in plastic buckets, barrels, or boxes with lids that may be secured tightly. These containers should be lined with plastic bags that are tied or otherwise sealed. Infectious waste containers should be strapped securely on a roof cargo rack or in the cargo compartment of a vehicle. Loose containers are more likely to be damaged or tossed from the vehicle.

4. Disinfect waste bags and containers – Prior to moving infectious waste bags or containers the exterior should be sprayed with a disinfectant. After transporting infectious waste containers, all containers that will be reused must be disinfected.
5. Disinfect all vehicles surfaces where infectious waste containers were stowed.
6. Use a disinfectant known to kill the pathogens likely to be found in the waste.

Section 2.5.3. Best Options for Disposal of Infectious Materials and Carcasses

The best option for disposal of infectious material must be carefully evaluated, including consultation with local environmental and health authorities. Local permits may be required for disposal of necropsy or infectious waste. Options for infectious waste or carcass disposal and the rationale for each option are described below.

OPTION 1: Delivery of Waste to a Health Facility for Safe Disposal

This is generally the best option when:

1. The volume of infectious waste is limited to the number of plastic bags or containers that can be properly secured on the available transport vehicle. The volume of waste associated with most daily field sampling activities fits in this category. (Necropsy waste from medium to large-sized animals may not fit in this category).
2. The waste can be delivered to the health facility for disposal within 48 hours. The longer waste is temporarily stored, the greater the risk that the containment bags or containers will break and expose humans and other animals to infectious materials.
3. The local health facility has agreed to dispose of the waste and is expecting your delivery of infectious waste.
4. A transport vehicle is available with either a roof rack or outside bed in which to transport the infectious waste containers. Do not transport infectious waste bags or containers in the passenger compartment of a vehicle. All materials transported must be securely attached to the vehicle so that containers will not break or spill from the vehicle.

To Deliver Infectious Waste to a Health Facility for Disposal:

1. Secure an agreement with the facility to accept waste. This agreement should include the costs, delivery times, and infectious waste containment requirements.
2. Be sure have available the required PPE, disinfection and containment materials necessary to safely contain and transport waste: masks, gloves, coveralls, sharps containers, sturdy plastic bags and ties, disinfectant spray, buckets with tight fitting lids, and/or liquid waste containers as needed.
3. Check vehicle and vehicle cargo space requirements for anticipated waste bags and containers. Sealed bagged or bottled waste should be transported in outside racks or cargo areas rather than inside vehicle passenger compartments. All such materials should be secured so they are unlikely to break open or fall off the vehicle.
4. Notify the authorities of the facility to which the infectious material will be delivered in advance of the scheduled sampling activities, so they may anticipate your delivery of infectious materials.

5. Contain and deliver the waste to the facility in accordance with the guidelines of the facility. It is recommended that high-risk waste be triple-bagged and sprayed with 10% sodium hypochlorite solution to disinfect the outside of the bags. Contaminated waste may include gloves, mask, face shield, Tyvek suits and other soiled and disposable materials. The triple-bagged materials are delivered to a facility for appropriate disposal.
6. Disinfect the transport vehicle immediately after each delivery.

OPTION 2: Field Disposal—Burning and Burying of Infectious Materials

Under certain circumstances, field disposal may be the best (safest and most practical) option for disposing of carcasses, necropsy waste and other infectious materials as long as field disposal (burning and burying) can occur in the vicinity of the site where the waste was generated. Burying waste contained in plastic bags, without burning, will likely allow pathogens to survive longer, posing greater risk of exposing people and animals. The best option for carcass disposal may be burning and burying, just burying, or just leaving the carcass where it is found.

Criteria for Choosing a Field Disposal (Burn and Bury) Method

Field disposal may be the best option when:

1. The volume of infectious waste exceeds what can be safely contained and transported to a health facility for disposal. This may include large amounts of necropsy waste or liquid waste, or animal carcasses. Moving the infectious materials poses great risk of spreading the infection to other areas.
2. It is not possible to transport the waste to a facility for disposal within 48 hours.
3. There is no vehicle with adequate cargo space for the waste bags or containers.
4. There are places nearby where waste can be safely buried.

Considerations for Determining the Best Site to Burn and Bury Infectious Materials

1. Nature and amount of material for disposal (size and quantities of waste).
2. Availability of sites nearby suitable for digging a waste pit and burning waste, away from houses and other structures that constitute human communities.
3. Accessibility of site by the vehicle used to move the waste.
4. Features of the soil (i.e., easy to dig), low to no slope.
5. Depth of groundwater: water table level should be at least 1.5 meters below the bottom of the pit.
6. At least 50 meters from water catchments, bore holes and wells.
7. Away from livestock, poultry or dogs.
8. Away from wildlife that may dig up the material.
9. Risk that humans may dig up the material.
10. Subsequent plans for use of the area.
11. Whether or not fencing will be required to exclude animals.

Procedure for Burning and Burying Infectious Waste and Necropsy Waste

1. The pit placement should not be dug in wet (swampy) soil and should be at least 50 m from any water source or human habitation.
2. Wear PPE (gloves, masks, goggles and apron or dedicated clothing) when handling or moving a carcass for burial, and while burning and burying the waste.
3. Contain infectious necropsy waste and other infectious materials in sealed plastic bags. Spray the exterior of the bags with disinfectant prior to handling or moving to the burn-burial pit.
4. Dig a hole, generally at least 1.5 m to 2 m deep-- enough to allow the waste to be covered with soil to a depth of 1m. Place wood fuel in the pit prior to placing the waste bags in the pit. (See the Illustration below for dimensions of a burn-burial pit).
5. Pour a cup of diesel fuel (gasoil) over the waste material and wood fuel and ignite carefully with a torch on a stick, while staying clear of the fire pit. (If burning waste repeatedly at a base compound consider building a 220-liter (55-gallon) steel drum waste incinerator as specified by WHO-CDC (see below).)
6. The fire should be tended with a long stick to move burning contents to ensure all is burned. Fuel may need to be added to completely burn all waste.
7. Disinfect shovels and any other reusable equipment or containers used to move and bury the waste. Disinfect with 70% ethanol (metal items like the shovel) or 10% bleach (plastic or rubber items like boots).

Procedure for Burning and Burying Carcasses

1. Place the animal material in a safe place, at least 100 meters from human settlements, and at least 50 m from any water source (stream, well, etc.).
2. If diesel fuel (gasoil) is being used, place the carcass/parts in a shallow (10 cm) deep hole to help contain the burn.
3. If using brush or wood as fuel, make sure that it is dry enough to burn easily.
4. Typically a pyre is constructed, with the carcass/parts placed on top of a large pile of fuel.
5. In either case, the carcass/parts should be burned until reduced to ashes.
6. Shovel dirt over the remaining ashes to completely cover them.
7. Disinfect shovels and any other reusable equipment or containers used to move and bury the waste. Disinfect, with 70% ethanol, metal items like the shovel or with 10% bleach for plastic or rubber items like boots.

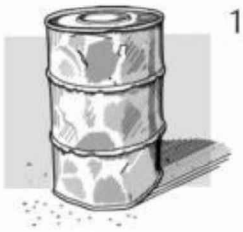
Procedures for Burying Carcasses

1. Wear PPE (gloves, masks, goggles and apron or dedicated clothing) when handling or moving a carcass for burial.
2. The pit should not be dug in wet (swampy) soil and should be at least 50 m from any water sources.
3. Dig a pit, generally at least 1 m (and ideally 2 m) deep enough to allow the carcass to be covered with at least 60 cm of soil.
4. Disinfect shovels and any other reusable equipment or containers used to move and bury the waste. Disinfect with 70% ethanol metal items like the shovel or with 10% bleach for

plastic or rubber items like boots.

CDC-WHO Procedure for Building a Barrel Waste Incinerator

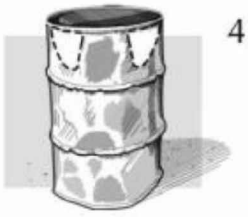
Steps for Building an Incinerator



1 Find a 220-litre (55-gallon) drum.

2 Cut open the drum. Remove and save the top cutaway piece.

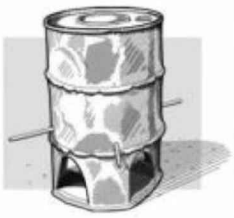
3 Hammer the edges of the drum so they are not sharp.



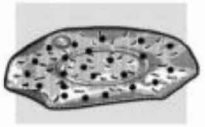
4 Cut 3 half-moon openings just above the top end of the drum.

5 Turn the drum upside down. The bottom of the drum now is the top.

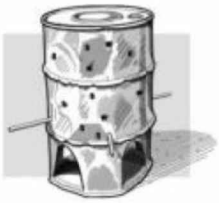
6 Cut 4 holes on the sides of the drum. Thread 2 metal rods through these holes so that they cross inside the drum.



7 Punch holes in the top cutaway piece to make a platform.



8 Pierce a series of holes on the side of the drum and above the crossed rods to improve the draw of the fire.



9 Cut away half of the top. Attach the wire loops to the cutaway half to make a trap door. Attach another loop for a handle to open the trap door.

10 Place the platform inside the drum on top of the rods.

OPTION 3: Leave an Infectious Carcass Where It Is Found

Leaving a carcass where it is found may be the best option when:

1. The carcass is not near people or domestic animals
2. The animal carcasses are large or numerous such that it is not safe or practical to move and bury them. For example, there may be numerous large animals during a disease outbreak. In this case, local authorities will decide how to deal with the carcasses.

Considerations to Leave Infectious Carcasses Where They are Found

The safest and most practical option for handling an infectious animal carcass or numerous carcasses may be to leave them where they are found. If the decision is made to not move a carcass that may be infected with a dangerous pathogen, local public health and animal health officials should be notified of the location and suspected infectious risk of the carcasses.